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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,157	05/01/2001	Michael D. Smith	0942.5040001/RWE/MTT	2674
26111	7590	11/04/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,157	Applicant(s) SMITH ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 12, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 7-29, 44-47, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8, 9, 19-23, 25 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 7, 10-18, 24, 26-28, 44-47, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2004 has been entered.

Status

2. Claims 2-4,7-29,44-47,51 and 52 are pending.

Claims 2, 3, 7, 10-18, 24, 26-28, 44-47, 51 and 52 are rejected.

Claims 4,8,9,19-23,25 and 29 are withdrawn from consideration.

With regard to status identifiers for the withdrawn claims, it is probably better practice to indicate the claims as –withdrawn, currently amended- than simply currently amended-.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Claim Interpretation

3. The claims, as most recently amended, now include SEQ ID NO: 8. This sequence defines a wild type MMLV reverse transcriptase.

First, a careful consideration of whether this is a proper incorporation by reference indicates that this examiner believes the incorporation to be proper. That is,

the reference to a patent, U.S. Patent 5,668,005, which describes a single wild type sequence that is identical to SEQ ID NO: 8, and whose paragraph ends with the request for incorporation by reference, appears to meet the requirements. The unpublished Federal Circuit decision, *Southern Clay Products Inc. v. United Catalysts Inc.*, 64 USPQ2d 1606, 1610 (CAFC 2002) suggests that identifying the subject matter is sufficient, with the Court noting at page 1610 "Southern Clay asserts that merely citing to a reference is not sufficient for incorporation of it, and that Clocker does not clearly identify which material in Cohn is meant to be incorporated. See *Advanced Display*, 212 F.3d at 1282-83, 54 USPQ2d at 1679; *Application of Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973). We disagree. Clocker specifically identifies that Cohn is relevant for its bond-breaking methods." This is similar to the current case, where the specification specifically identifies U.S. Patent 5,668,005 as describing reverse transcriptases with reduced RNase H activity. Therefore, the incorporation by reference is permitted.

Second, the question arises with regard to the Blain and Arakawa references of whether these claims require a reverse transcriptase without a methionine at the amino terminal position. Not only do the claims not state that there is not a methionine at the amino terminus, but SEQ ID NO: 8 clearly has a methionine at the amino terminus. Thus, the claims will be read with SEQ ID NO: 8 as the base material.

Claim Rejections - 35 USC § 112, second paragraph

4. The rejection of claims 16-18 and 24 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

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5. Claims 2, 3, 7, 10-18, 24, 26-28, 44-47, 51 and 52 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite how, for example, a leucine 52 can be substituted in claim 2 (from which all of the current claims depend), when the amino acid at position 52 in SEQ ID NO: 8 is a proline. So the numbering of the sequences in the claim relative to the numbering in the SEQ ID NO are not consistent and this renders the claim vague and indefinite because it becomes unclear whether the substitution should then be at position 52, which is a proline in SEQ ID NO: 8, at position 53, which is a leucine or at position 49 which is a leucine. The solution to this dilemma may be to import the language from the end of paragraph 0161 into claim 2, such that after "(SEQ ID NO: 8)" the claim could state "wherein amino acid number 1 of the wild type M-MLV reverse transcriptase of SEQ ID NO: 8 is the threonine following the initial methionine." This has support from the specification and would not be new matter. Other similar language might also be acceptable.

Claim Rejections - 35 USC § 112 – Written Description

6. The rejection of claims 2, 3, 7, 10-18, 24, 26-28, 44-47, 51 and 52 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The rejection of claims 2, 3, 16-18, 24, 26, 27 and 28 under 35 U.S.C. 102(b) as being anticipated by Blain et al (J. Biol. Chem. (1993) 268(31):23585-23592) is withdrawn in view of the amendment.

9. Claims 2, 3, 12-18, 24 and 26-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Arakawa et al (JP 2000-139457, published May 23, 2000).

Arakawa et al teach altered MMLV reverse transcriptases which have expressly shown reduced RNase H activity (see translation, page 2 of 9, paragraph 0008) which retains enhanced DNA polymerase activity (see translation, page 2 of 9, paragraph 0009) and expressly teaches thermostability at 60 C of the modified enzyme which retains significant activity at 60 C (see abstract and translation, page 6 of 9). Further, as a review of the sequence of Arakawa shows (see page 9-10 of Japanese text), amino acid 52 is proline, not leucine. Further, the amino acid at 204 is Leucine, not histidine, and the position at 289 is valine and the position at 306 is Glycine. Thus, Arakawa teaches modifications at each of the cited positions.

10. The rejection of claims 2, 12-18, 24 and 26-28 under 35 U.S.C. 102(b) as being anticipated by Lawyer et al (J. Biol. Chem. (1989) 264(11):6427-6437) is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 44-47, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa et al in view of Stratagene Catalog (1988) p. 39.

Arakawa et al teach altered MMLV reverse transcriptases which have expressly shown reduced RNase H activity (see translation, page 2 of 9, paragraph 0008) which retains enhanced DNA polymerase activity (see translation, page 2 of 9, paragraph 0009) and expressly teaches thermostability at 60 C of the modified enzyme which retains significant activity at 60 C (see abstract and translation, page 6 of 9). Arakawa teaches the use of RT's in RT-PCR (see page 1 of 9 of translation).

Arakawa does not teach formation of a kit with these known reagents.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method and products of Arakawa into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Claim Rejections - 35 USC § 112 – New Matter

14. The rejection of claims 2, 3, 7, 10-18, 24, 26-28, 44-47, 51 and 52 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment.

Response to Arguments

15. Applicant's arguments filed October 12, 2004 have been fully considered but they are not persuasive.

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Applicant argues that the claims, which expressly incorporate SEQ ID NO: 8, require that the polymerase not have a methionine at the amino terminal end. This is not a limitation in the claim. The fact that Applicant apparently uses a different numbering scheme does not distinguish the prior art given the current claims. It is suggested that if Applicant wishes to use a numbering scheme in which position 52 is a leucine, then the claim be amended to reflect this point. In fact, as noted in the 112, second paragraph rejection above, the claims make no sense when referring to SEQ ID NO: 8 as having a leucine at position 52 because there is a proline at that position. So the claims remain rejected under the Arakawa reference since limitations from the specification are not read into the claims.

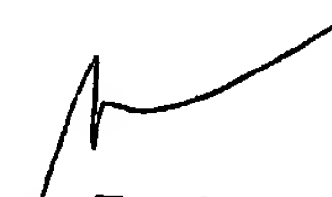
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman
Primary Examiner
Art Unit 1637

16/30/04